

REMARKS

The undersigned attorney thanks the Examiner for the personal interview conducted on August 21, 2003. During this interview, the differences between the Larsen system (U.S. patent 5,968,011) and the present invention were discussed.

As reflected in the August 21, 2003 Interview Summary, the Examiner agreed to consider further argument. Such argument is presented below.

THE PRESENTLY CLAIMED INVENTION

Independent claims 1 and 17 specifically set forth a device having two main parts, being: (1) a housing with a generally flat bottom; and (2) a connecting hub with a Y-shaped internal flow channel.

The housing is placed against the patient's skin, and the connecting hub (to which an infusion pump line may be attached) is then manually connected into the housing.

As such, it is important to note that the **Y-shaped flow channel is found in the connecting hub, and not in the housing** that is placed against the patient's skin.

THE LARSEN '011 SYSTEM

Larsen describes a two part device having a base element 1 and a rotatable top element 2. By rotating top element 2, the flow through the device can selectively be turned on and off, as follows. Flow enters the device through hose 5. When top element 2 is rotated to an "open" position (as shown in Figs. 11 and 13) aperture 19 is positioned such that flow is permitted between bore 34 and entry lumen 25. Conversely, when top element 2 is rotated to a "closed" position (as shown in Figs. 12 and 14) aperture 19 is positioned to block flow between bore 34 and entry lumen 25. An operator is provided with large contoured arms 16 on top element 2 such that top element 2 can conveniently be rotated from a "closed" position to an "open" position.

An additional feature of the Larsen system is that needle hub 3 and its attached needle 14 (illustrated together in Fig. 18) are removable. Thus, as can be seen in Figs. 11

and 12, needle hub 3 and needle 14 can conveniently be removed after the device has been positioned on the patient's skin.

THE EXAMINER'S COMMENTS

During the personal interview of August 21, 2003, the Examiner made particular mention of Larsen's Fig. 11, stating that once needle hub 3 and needle 14 are removed, the presently claimed "Y-shaped" flow channel could be provided by the Larsen system, as follows.

According to the Examiner, the end of an auxiliary needle (not shown) could conceivably be introduced through aperture 7 and septum 35 after needle hub 3 has been removed, such that a "Y-shaped" flow channel is provided (with flow entering both through hose 5 and through the auxiliary needle in aperture 7 mixing and exiting through cannula 13).

As agreed by the Examiner, it is not possible to have a Y-shaped flow path unless needle hub 3 is first removed. Specifically, as can be seen in Fig. 7, flow enters through hose 5 and exits through the bottom end of needle 14, however, flow must be blocked through the upper portion of needle 14 that is disposed within hub 3. This is because if the portion of needle 14 disposed within hub 3 were open to flow therethrough, medication entering through hose 5 would simply tend to seep out the top of hub 3 when the device is in use. Moreover, any free flow through the upper portion of needle 14 disposed within hub 3 would result in an unsterilized opening into the patient's body such that the patient's own blood could also tend to seep out the top of hub 3.

APPLICANTS RESPONSE TO THE EXAMINER'S COMMENTS

The Examiner's above assertion that an auxiliary needle placed into aperture 7 may constitute a form of Y-shaped flow channel in base element 1 may or may not be true.

In any event, the presently claimed invention specifically sets forth the Y-shaped flow channel being in its **"connecting hub"**, as opposed to being in the flat bottomed **housing** that is positioned against the patient's skin.

There are a number of advantages in having the Y-shaped flow channel be in the connecting hub, as claimed, as opposed to being in the housing itself. First, such a design permits the presently claimed Y-shaped flow channel connecting hub to be interchanged with new Y-shaped flow channel connecting hubs whenever such connecting hubs begin to show signs of wear and tear. Alternatively, the presently claimed Y-shaped flow channel connecting hub can be interchanged with a more standard connecting hub (such as a single straight through flow channel), as desired.

Secondly, an advantage of placing the Y-shaped flow channel in the connecting hub is that such design permits the auxiliary needle to enter the connecting hub at an angle generally parallel to the surface of the patient's skin. In contrast, any auxiliary needle entering hole 7 of the Larsen system would need to enter at an angle generally perpendicular to the surface of the patient's skin. The Applicant's design is therefore more convenient to operate.


CONCLUSION

For the reasons presented above, all claims are believed to be in condition for allowance. A Notice of Allowance is therefore respectfully requested.

Should the Examiner feel that a telephone conference would advance prosecution of the present application, he is invited to call the undersigned attorney at the number listed below.

Respectfully submitted,

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